DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

February 12, 2015

Smith & Nephew Incorporated
Ms. Shereen Bienz
Senior Regulatory Affairs Specialist
7135 Goodlett Farms Parkway
Cordova, Tennessee 38016

Re: K143226
Trade/Device Name: VISIONAIRE™ Disposable Instruments
Regulation Number: 21 CFR 888.3560
Regulation Name: Knee joint patellofemorotibial polymer/metal/polymer semi-constrained cemented prosthesis
Regulatory Class: Class II
Product Code: JWH, MBH
Dated: November 26, 2014
Received: November 28, 2014

Dear Ms. Bienz:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing

(21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Mark N. Melkerson -S

Mark N. Melkerson
Director
Division of Orthopedic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Premarket Notification
Indications for Use Statement

510(k) Number (if known): _K143226_____

Device Name: VISIONAIRE™ Disposable Instruments

Indications for Use:

Smith & Nephew's VISIONAIRE™ Disposable Instruments are intended to be used to further prepare the bone and assist in the positioning of total knee replacement components intra-operatively. Smith & Nephew VISIONAIRE™ Disposable Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Genesis II and Legion knee systems and their cleared Indications for Use.

The contraindications, potential adverse events, precautions, and warnings for the knee systems can be found in the Smith & Nephew Knee System package insert. The VISIONAIRE™ Patient Matched Cutting Blocks and Disposable instruments are intended for single use only. Do not reuse due to risks of breakage, failure or patient infection.

Prescription Use __X__ AND/OR Over-the-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

_____ ____

(Division Sign Off)
Division of Orthopedic Devices
510(k) Number: K143226

We are smith&nephew

Submitted by:	Smith & Nephew, Inc. Orthopaedic Division 1450 East Brooks Road Memphis, Tennessee 38116
Date of Summary:	January 2, 2015
Contact Person and Address:	Shereen Bienz Senior Regulatory Affairs Specialist T 901.399.6325 F 901.566.7075
Name of Device:	Smith & Nephew, Inc. Disposable Instruments
Common Name:	Orthopaedic Surgical Instrumentation
Device Classification Name and Reference:	21 CFR 888.3560 Knee joint patellofemorotibial polymer/metal/ polymer semi-constrained cemented prosthesis 21 CFR 888.3565 Knee joint patellofemorotibial metal/polymer porous-coated uncemented prosthesis
Device Class:	Class II
Panel Code:	Orthopaedics/87
Product Code:	JWH, MBH

Device Description

Per U.S. Food and Drug Administration (FDA) regulation, device-specific instruments are accessory devices and take on the classification of the device(s) with which they are used. Although these instruments are similar in design to 510(k)-exempt orthopaedic manual instruments classified under 21 CFR 888.4540, instruments which assist in the implantation of Class II Smith & Nephew Total Knee Systems and are classified as Class II devices are subject to pre-market notifications and regulations.

The Smith & Nephew Disposable Instruments include line additions to the Smith & Nephew Disposable Knee Instruments that were cleared in K123159. The subject devices are intended prepare the bone for Total Knee Arthroplasty.

Intended Use

Smith & Nephew's VISIONAIRE™ Disposable Instruments are intended to be used to further prepare the bone and assist in the positioning of total knee replacement components intra-operatively. Smith & Nephew VISIONAIRE™ Disposable Instruments are accessory devices and are intended to be used to assist in the implantation of Smith & Nephew Genesis II and Legion knee systems and their cleared Indications for Use.

The contraindications, potential adverse events, precautions, and warnings for the knee systems can be found in the Smith & Nephew Knee System package insert. The VISIONAIRE™ Patient Matched Cutting Blocks and Disposable instruments are intended for single use only. Do not reuse due to risks of breakage, failure or patient infection.

Table 5.1 includes the Smith & Nephew Total Knee Systems to be used in conjunction with the subject device.

Table 5.1 Smith & Nephew Inc. Compatible Total Knee Systems

Description	510(k)	Clearance Date
LEGION PRIMARY SYSTEM	K093746	04/14/2010
GENESIS II TOTAL KNEE SYSTEM	K951987	08/22/1995
GENESIS II P/S HIGH FLEXION KNEE INSERT	K032295	08/21/2003
GENESIS II DEEP FLEXION C/R ARTICULAR INSERT	K041825	03/11/2005
TOTAL KNEE SYSTEM INSTRUMENTATION	K121393	08/07/2012
Disposable Knee Instruments	K123159	05/03/2013
Smith & Nephew Disposable Fin Punch	K141585	08/21/2014

Technological Characteristics

Biocompatibility testing for the new colorants and materials was conducted per the recommendations of ISO 10993-1. A review of the results indicates that the Disposable Instruments are equivalent to existing, legally marketed predicate instrumentation with regards to mechanical performance and that there are no new issues related to the safety and effectiveness of the subject devices. Clinical data was not needed to support the safety and effectiveness of the subject devices.

Substantial Equivalence Information

The Smith & Nephew Disposable Instruments are line additions to the Smith & Nephew Disposable Knee Instruments that were cleared in K123159. Smith & Nephew Disposable Knee Instruments cleared in K123159 are comprised of the following instrument types with their respective purposes described in the following table. In addition, the material composition of the subject devices is identical to the instruments cleared via premarket notification K123159.

Table 5.2 Substantially Equivalent Predicates to the Disposable Instruments

Manufacturer	Description	Submission Number	Clearance Date
Smith and Nephew Inc.	Disposable A-P Cut Block	K123159	05/03/2013
Smith and Nephew Inc.	Disposable Ream through Trial	K123159	05/03/2013
Smith and Nephew Inc.	Disposable Tibia Base Plate Trial	K123159	05/03/2013
Smith and Nephew Inc.	Disposable Cam Module	K123159	05/03/2013
Smith and Nephew Inc.	Disposable Insert Trials	K123159	05/03/2013

Conclusion

As previously noted, this Traditional 510(k) Premarket Notification is being submitted to request clearance for the Smith and Nephew Disposable Instruments. Based on the similarities to the predicate devices and a review of the testing performed, the devices are substantially equivalent to above predicate Total Knee Instrumentation.